June 28, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+NETT/SIREN Study Coordinator Call

July 9th at 1pm ET

+NETT/SIREN Steering Committee Call

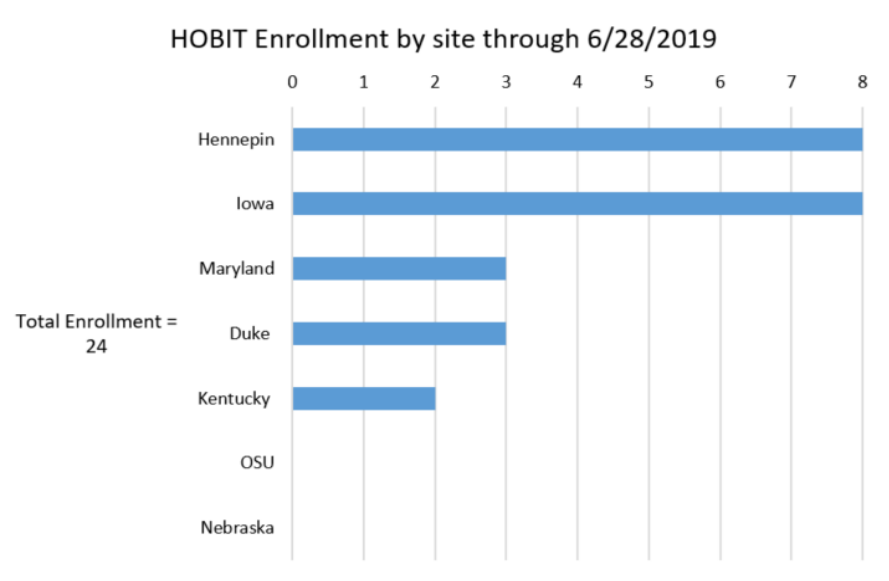
July 24th at 12pm ET

Iowa — 2 Participants Enrolled

Big kudos to the University of Iowa Hospital and Clinics on enrolling 2 participants this week!

HonorHealth—Simulation Approved & Readiness Call Scheduled

Nice work by HonorHealth Scottsdale Osborn Medical Center on completion of the simulation as well as scheduling their readiness call!



HOBIT Updates

MOP Updates

Update to section 3.4 Study Intervention; page 15 (new paragraph added)

For subjects randomized to the HBO + NBH or NBH only groups, a clinician should place an order for the NBH treatment. This will allow tracking of the start and stop times of NBH treatment.

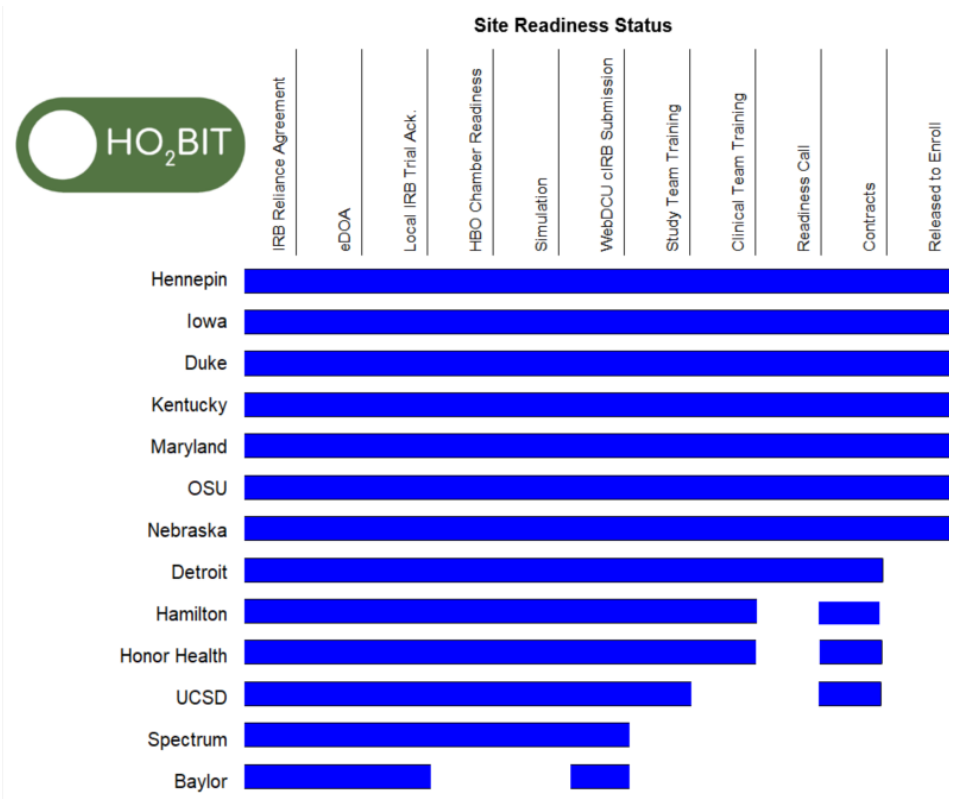
FAQ

A new FAQ has been added to the HOBIT website:

Q: Should death be considered an SAE?

A: No, death is considered an outcome. The event causing death should be reported as the SAE. For instance, if fulminant sepsis causes the death, sepsis should be considered the SAE.

If the subject dies after being withdrawn from life support and placed on comfort care secondary to their neurological injury, that should be reported in one of 2 ways. If they were deteriorating neurologically, the SAE should be reported as "neurological deterioration." In the vast majority of cases, the death should be reported this way. In the unusual circumstance that the subject remained neurologically stable or improved, the SAE may be reported as "withdrawn from life support." The GCS at the time of enrollment and the one closest to withdrawal from life support should be included in the SAE narrative.

Virtual Investigator Meeting Slides

We wanted to thank everyone who attended the Virtual Investigator Meeting! A special thank you to Duke, Hennepin, and Iowa who helped present during the meetings. The meeting slides are available on HOBIT website under the Investigator Meeting tab of the homepage (hobittrial.org). The slides can be used for anyone who may have missed the meeting and can also be used for education of clinical staff or other members of your study teams.